Notice of Allowability	Application No.	Applicant(s)	
	09/230,955	MASON ET AL.	
	Examiner	Art Unit	
	Karen A Canella	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☐ This communication is responsive to *amendment filed Jan 28, 2004*.

2. ☐ The allowed claim(s) is/are *1, 3, 4, 5, 7, 10, and 12, renumbered as 1-7, respectively*.

3. ☐ The drawings filed on _____ are accepted by the Examiner.

4. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
   a) ☒ All b) ☐ Some* c) ☐ None of the:
      1. ☐ Certified copies of the priority documents have been received.
      2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
      3. ☒ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

   * Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.

6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
   (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
      1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
   (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

   Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☐ Interview Summary (PTO-413), Paper No./Mail Date _____ .
7. ☒ Examiner's Amendment/Comment
8. ☐ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____.

Karen A. Canella

KAREN A. CANELLA PH.D
PRIMARY EXAMINER

EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Daniel Monaco on May 4, 2004.

The application has been amended as follows:

Claim 2 has been canceled.

Claim 1 has been substituted with the following:

1. A method of screening for a premalignant or neoplastic disease state in the squamous cells of a cervical smear sample containing columnar and squamous cells of the cervix, the method comprising

contacting said sample with a panel of two or more monoclonal antibodies, said panel of antibodies including at least one monoclonal antibody specific for columnar cells and at least one monoclonal antibody specific for squamous cells, wherein said panel of monoclonal antibodies binds to surface antigens of normal columnar and squamous cells;

verifying that the cervical sample comprises columnar cells by detecting the binding of the monoclonal antibody specific for columnar cells in the cervical sample;

comparing the pattern of binding of the panel of monoclonal antibodies in said sample with the pattern of binding of said monoclonal antibody panel to a normal cervical cell sample, wherein an alteration of the pattern of binding of the monoclonal antibody or antibodies which bind to squamous cells in the cervical smear sample relative to the pattern of binding of the monoclonal antibody or antibodies which bind to squamous cells in a normal cervical cell sample is indicative of a premalignant or neoplastic disease state

Claim 3 has been substituted with the following:

3. A method of screening for a premalignant or neoplastic disease state in the squamous cells of a cervical smear sample containing columnar and squamous cells of the cervix, the method comprising

contacting said sample with a panel of two or more monoclonal antibodies, said panel of antibodies including at least one monoclonal antibody specific for columnar cells and at least one monoclonal antibody specific for squamous cells, wherein said panel of monoclonal antibodies binds to surface antigens of normal columnar and squamous cells;

verifying that the cervical sample comprises columnar cells by detecting the binding of the monoclonal antibody specific for columnar cells in the cervical sample;

comparing the pattern of binding of the monoclonal antibody or antibodies which bind to squamous cells in the cervical smear sample with the pattern of binding of said monoclonal antibody or antibodies which bind to squamous cells in a normal cervical cell sample, wherein an alteration of the pattern of binding is indicative of a premalignant or neoplastic disease state and wherein the panel includes one or more monoclonal antibodies comprising an antigen binding domain obtainable from a hybridoma selected from those deposited at the European Collection of Animal Cell Cultures (ECACC), under the accession numbers ECACC 95020718, ECACC 95020716, ECACC 95020720, ECACC 95020717 and ECACC 95020719.

Claim 4 has been substituted with the following:

4. A method according to Claim 1 wherein one or more of the monoclonal antibodies bind to an antigen which can be bound by one or more antibodies obtained from a hybridoma selected from those deposited at the European Collection of Animal Cell Cultures (ECACC), under the accession numbers ECACC 95020718: ECACC 95020716: ECACC 95020720, ECACC 95020717 and ECACC 95020719.

Claim 7 has been substituted with the following:

7. A monoclonal antibody which specifically binds to the surface or normal squamous or columnar cells or the cervix comprising an antigen binding domain obtainable from a hybridoma selected from those deposited at the European Collection of Animal Cell Cultures (ECACC),

under the accession numbers ECACC 95020718, ECACC 95020716, ECACC 95020720, ECACC 95020717 and ECACC 95020719.

Claim 10 has been substituted with the following:

10. The method as claimed in Claim 1 wherein said panel of monoclonal antibodies comprises a monoclonal antibody having an antigen binding domain obtainable from a hybridoma deposited at the European Collection of Animal Cell Cultures (ECACC) under the accession number ECACC 95020716.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen A Canella whose telephone number is (571)272-0828. The examiner can normally be reached on 10 a.m. to 9 p.m. M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached on (571)272-0871. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Karen A. Canella, Ph.D.
Art Unit 1642
04/08/04

KAREN A. CANELLA PH.D
PRIMARY EXAMINER